

REMARKS

The claims have been amended to provide improved syntax as well as to more clearly define the invention. The "control sheath" is now referred to as the "control element". Claims 13 and 14 have been added.

CLAIM OBJECTIONS

Claim 10 has been amended as suggested by the examiner to correct a typographical error.

THE INVENTION

Applicants' invention relates to improvements in endoscope accessories and control systems for such accessories. In particular, the invention relates to an accessory of the type having an operating device mountable to the distal region of the endoscope with a control system for operating the device in which the user can manipulate both the endoscope shaft and the distal operating device with a single hand. The invention enables a physician to operate the endoscope and the accessory without the assistance of another person. Additionally, the invention enables such single-operator use without obstructing or otherwise adversely affecting the availability of the working channel of the endoscope for other functions.

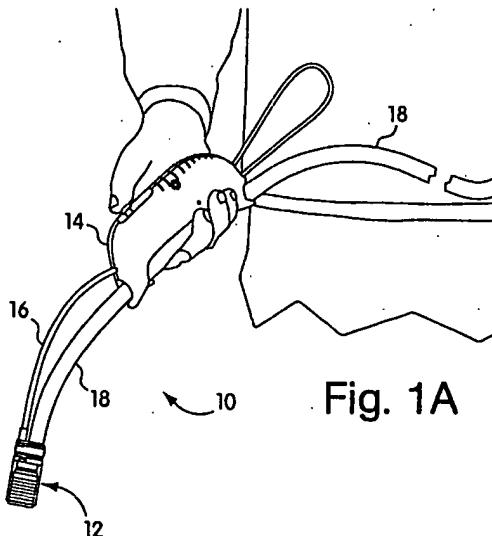


Fig. 1A

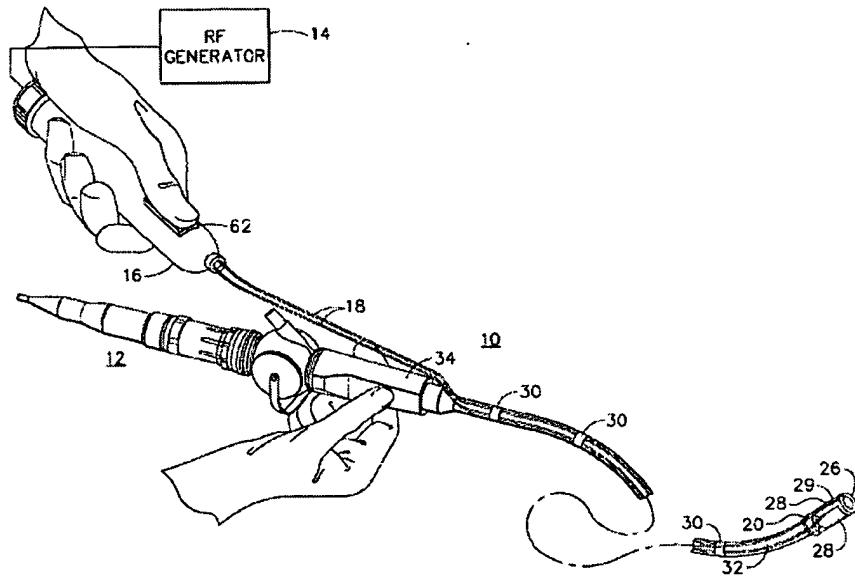
Fig. 1A shows the control system 10 includes the endoscope accessory having an operating device 12, a control handle 14 for operating the accessory, and a control element 16 extending from the control handle to the operating device of the accessory. As shown in Figs. 1A, 1B and 7, the control handle 14 is configured to be detachably mountable to the endoscope shaft for movement along the shaft. The control element may include a sheath that houses control members that extend from controls on the handle to the operating device on the distal end of the endoscope.

The handle is configured to enable the physician to grip directly and manipulate the handle and the endoscope shaft with one hand, leaving the other hand free to manipulate the endoscope controls at the proximal end of the endoscope. That contrasts with prior devices that require a second person (i.e., a third hand) to simultaneously manipulate the endoscope shaft, the endoscope controls and the accessory controls.

THE CITED ART

Long (U.S. App. No. 2002/0177847)

U.S. App. No. 2002/0177847 to Long discloses an endoscopic ablation system for use with a flexible endoscope. As shown in Fig. 1, reproduced below, the arrangement includes a flexible endoscope 12 having an endoscope handle 34 with endoscope controls and a flexible shaft 32. A separate endoscope ablation system 10 that includes an ablation cap 20 that fits over the distal end of the endoscope shaft 32 and a plurality of conductors 18 that are attached to the endoscope shaft by a plurality of clips 30. The ablation cap 20 includes a plurality of electrodes 28. The ablation system also includes a handpiece 16 that includes a switch 62 and a generator 14 by which electrical energy can be transmitted to the electrodes to effect tissue ablation. Although the handle 16 of the ablation system is connected to the conductors 18, the handpiece 16 itself is not attached or connected to the endoscope shaft or any other part of the endoscope.



THE REJECTIONS

Claim Rejections Under 35 U.S.C. § 103

Reconsideration is requested of the rejection of claim 1 as defining subject matter that would have been obvious in view of Long. While Long may be considered as disclosing an endoscopic accessory and a system for controlling operation of the accessory, it does not disclose several features of applicants' claimed invention. Additionally, the rejection does not point to any evidence of a motivation to modify the Long device in any manner, much less in the manner of applicant's invention. In particular, Long does not disclose any of the following of applicants' claimed features:

- A handle that is mountable to and movable along the shaft of the endoscope.
- A handle that enables the physician to grip directly, with one hand, both the control handle and a portion of the shaft of the endoscope to enable the physician to simultaneously manipulate both with one hand.

Moreover, Long is not directed to the solution of the same problem with which applicants' invention is concerned. It seems clear from Fig. 1 of Long that the physician will

require one hand to operate the RF generator and the other hand to operate the controls on the proximal handle of the endoscope.

Advancement and manipulation of the endoscope shaft, therefore, will require the assistance of another person. Long, therefore, presents precisely the kind of difficulty that applicants' invention is intended to overcome.

To the extent that the rejection relies on the notion that "...Long discloses that the handpiece 16 is configured to be mounted laterally to the shaft 32 of the endoscope between the proximal and distal ends,..." that is incorrect. The Long handpiece 16 does not mount to any portion of the endoscope shaft. No portion of the Long ablation accessory is movably mountable to the endoscope shaft. The claim does not require, as stated in the rejection, that the handpiece is configured to be mounted "laterally to the shaft 32 of the endoscope".

Long is the sole and only evidence on which the rejection is based. In cases where a single prior art reference is alleged to render the claimed invention obvious, there must be a sufficient showing of a suggestion or motivation for any modification of the teachings of that reference necessary to teach the claimed invention in order to support the obviousness conclusion. *Sibia Neuroscis., Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1356, 55 U.S.P.Q.2d 1927, 1931 (Fed. Cir. 2000); *B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1582, 37 U.S.P.Q.2d 1314, 1318 (Fed. Cir. 1996). This suggestion or motivation may be derived from the prior art reference itself, from the knowledge of one of ordinary skill in the art, or from the nature of the problem to be solved. *Sibia*, 225 F.3d at 1356, 55 U.S.P.Q.2d at 1931; *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 60 U.S.P.Q.2d 1001 (Fed. Cir. 2001). There is nothing in the action or in Long to evidence the requisite motivation.

Reconsideration is requested of each of claims 2-4, 6, 8 and 9. Each of those claims depends directly or indirectly from claim 1 and is patentable over Long for the same reasons. Additionally, Long does not disclose or suggest, and there is no evidence suggesting that Long should be modified to include:

- a control handle slidable along an endoscope shaft (claim 2);

- a control handle removably mountable to an endoscope shaft (claims 3 and 4);
- a control handle configured to be mounted laterally onto the endoscope shaft (claim 6); and
- the arrangement by which the user can grasp directly with one hand both the handle and the endoscope shaft to which the handle is mounted (claim 8).

Method claims 10-12 are directed to the method of operating an endoscope and a medical device accessory and include the limitations of providing an accessory control system that is externally mountable to an endoscope and with one hand, operating the endoscope controls at the proximal end of the endoscope and with the other hand operating both the accessory control on the endoscope shaft at a location between the proximal and distal ends of the shaft. The rejection fails to provide any evidence that Long discloses or suggests these methods.

Claims 13 and 14 have been added and depend from claims 5 and 1, respectively.

All of the claims are in condition for allowance. Please apply any charges or credits to Deposit Account No. 50-1721, Reference No.: 0506766.0218.

Respectfully submitted,



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Date: FEBRUARY 28, 2006